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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,645	07/05/2001	Chun Ping Li	35718/235742 (5718-114)	7724
826	7590	10/21/2003	EXAMINER	
			KALLIS, RUSSELL	
		ART UNIT	PAPER NUMBER	16
		1638		
DATE MAILED: 10/21/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/899,645	LI ET AL.
	Examiner Russell Kallis	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 31 July 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 4,15,16,18-20,23 and 31-36 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3,5-14,17,21,22 and 24-30 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6,7</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-3, 5-14, 17, 21-22, and 24-30 are to be examined. Claims 4, 15-16, 18-20, 23 and 31-36 are withdrawn from examination. Claims 1-36 are pending.

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1-3, 5-14, 17, 21-22, and 24-30 in Papers No. 13 and 15 is acknowledged. Further, upon election of SEQ ID NO: 1, Claims 4, 15-16, 18-20, 23 and 31-36 are withdrawn from examination. Claims 1-36 are pending.

The traversal is on the ground(s) that the methods of Groups I and II utilize the same starting materials. This assertion is incorrect because the method of decreasing the level of acyl-CoA thioesterase comprises antisense constructs which would be a different starting material than a sense construct. Further, the plants of the Groups I and II have different phenotypes resulting from the different methods. Applicant has also asserted that since GenBank Accession numbers AF124264 and AF124265 (SEQ ID NO: 3 and 5) are known sequences there is no burden upon the Examiner to consider these sequences in examining the methods of the invention when considering SEQ ID NO: 1. Extra sequence searches are a burden upon the resources of the Office and the Examiner. Since 1996 resources at the Patent office have changed, and the examination and search of more than one sequence would pose an undue burden. Finally, one sequence constitutes "up to ten".

The requirement is still deemed proper and is therefore made FINAL.

Applicant is reminded to amend elected claims to delete non-elected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-14, 17, 21-22, and 24-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant broadly claims a nucleotide sequence having at least 75% sequence identity to SEQ ID NO: 1.

Applicant only describes SEQ ID NO: 1 and SEQ ID NO: 2.

Applicant does not describe which 75% of the identity of SEQ ID NO: 1 is required to encode an acyl-CoA thioesterase or fragment thereof.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide an adequate written description of the claimed invention.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The court also addressed the manner by which genus of cDNAs might be described: “A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.” *Id.* At 1406.

Based upon the disclosure of SEQ ID NO: 1, there is insufficient relevant identifying characteristics to allow one skilled in the art to completely determine the structure of nucleic acid fragments or variants of SEQ ID NO: 1, other than SEQ ID NO: 1, that either increase or decrease the level of acyl-CoA thioesterase in a plant, including mutants and allelic variants, absent further guidance. Since the claimed genus encompasses undisclosed or yet to be discovered sequences that either increase or decrease the level of acyl-CoA thioesterase in a plant, the disclosure of SEQ ID NO: 1 does not provide adequate description of the claimed genus. In view of the level of knowledge and skill in the art one skilled in the art would not recognize from Applicant’s disclosure that Applicant was in possession of nucleic acid fragments or variants of SEQ ID NO: 1, other than SEQ ID NO: 1, that either increase or decrease the level of acyl-CoA thioesterase in a plant as broadly claimed.

Given the failure of a nucleotide sequence encoding a polypeptide having acyl-CoA thioesterase activity comprising at least 75% sequence identity to SEQ ID NO: 1 or fragment thereof to be adequately described wherein said sequences show an increase or decrease in activity, methods of its use are also inadequately described. See Written Description Guidelines, Federal Register Vol. 66 No. 4, Friday January 5, 2001 “Notices”, pages 1099-1111.

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Claims 1-3, 5-14, 17, 21-22 and 24-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims a method of decreasing beta-oxidation in a plant by transforming the plant with a nucleotide sequence encoding a polypeptide having acyl-CoA thioesterase activity that comprises 24 contiguous nucleotides of SEQ ID NO: 1 and a nucleotide sequence having at least 75% sequence identity to SEQ ID NO: 1.

Applicant teaches a cDNA from maize of SEQ ID NO: 1 homologous to the yeast PTE gene.

Applicant does not teach plants comprising a nucleotide sequence encoding a polypeptide having acyl-CoA thioesterase activity that comprises 24 contiguous nucleotides of SEQ ID NO: 1; a nucleotide sequence having at least 75% sequence identity to SEQ ID NO: 1; or a polynucleotide of SEQ ID NO: 1.

Given the unpredictability in the art as to which substitutions, deletions, or additions to SEQ ID NO: 1 would be tolerated; the breadth of the claims encompassing a nucleic acid encoding an acyl-CoA thioesterase having 24 contiguous nucleotides of SEQ ID NO: 1 or a nucleic acid encoding an acyl-CoA thioesterase having not less than 75% sequence identity to SEQ ID NO: 1; the lack of guidance in the examples of the specification or in the prior art as to which deletions, substitutions, insertions or additions would best serve the invention or which parts of SEQ ID NO: 1 would best confer thioesterase activity in a plant; although one of skill in the art can readily make nucleotide substitutions, additions, or deletions to a polynucleotide

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sequence one would not know based upon Applicant's disclosure which embodiments would be inoperable and predictable eliminated, and thus undue trial and error experimentation would be needed by one skilled in the art to make and clone a multitude of non-exemplified variants of SEQ ID NO: 1 and would require one of skill in the art to test in a myriad of non-exemplified plants for expression of a polynucleotide coding sequence to decrease beta-oxidation in a multitude of non-exemplified transformed plant species. Therefore, the invention is not enabled.

Claims 5-14, 17, 21-22 and 24-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims a method of decreasing beta-oxidation and increasing oil levels or a constituent thereof in a plant transformed with a nucleotide sequence encoding a polypeptide having acyl-CoA thioesterase activity that comprises 24 contiguous nucleotides of SEQ ID NO: 1 or with a nucleotide sequence having at least 75% sequence identity to SEQ ID NO: 1; and plants thereof wherein the level of acyl-CoA thioesterase activity is increased or decreased.

Applicant teaches a maize cDNA of SEQ ID NO: 1 homologous to the yeast PTE gene.

Applicant does not teach transformed plants comprising a nucleotide sequence encoding a polypeptide having acyl-CoA thioesterase activity that comprises 24 contiguous nucleotides of SEQ ID NO: 1; a nucleotide sequence having at least 75% sequence identity to SEQ ID NO: 1; or a polynucleotide of SEQ ID NO: 1 wherein the beta oxidation is decreased, the level of oil is increased, or the level of acyl-CoA thioesterase activity is increased or decreased.

The unpredictability of engineering a metabolic process in any higher organism such as a plant is made evident in the example of a transformation experiment where high levels of expression of a thioesterase from California Bay in *Brassica Napus* seeds had no effect on total oil content and limited laurate accumulation to 60% due to the regulation of the pathway of beta-oxidation (Eccleston V. *et al.*, The Plant Cell, April 1998, Vol. 10; pp. 613-621; see Abstract and page 619, columns 1 and 2).

Given the unpredictability in the art as to what regulatory mechanisms would be permissive of genetic engineering; the breadth of the claims encompassing changes in total oil content or a component of total oil; the lack of guidance in the examples of the specification or in the prior art as to how to alter thioesterase activity that would best confer both a reduction in beta-oxidation and an increase in oil levels or at least one constituent of plant oil composition; although one of skill in the art can readily transform plants with a polynucleotide sequence one would not know based upon Applicant's disclosure which embodiments would be inoperable and predictable eliminated, and thus undue trial and error experimentation would be needed by one skilled in the art to make a myriad of non-exemplified plants for expression of a acyl-CoA thioesterase polynucleotide coding sequence to decrease beta-oxidation in a multitude of non-exemplified transformed plant species that resulted in an increase in total oil or an increase in some unspecified oil component. Therefore, the invention is not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-14, 17, 21-22 and 24-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in all rejections.

In Claim 1, “a nucleotide sequence complementary to the nucleotide sequence” is indefinite. It is unclear if Applicant intends that the nucleotide sequence is complementary over the full length of SEQ ID NO: 1 or to some other undefined length of SEQ ID NO: 1.

In Claim 5, the claim recites “A method of decreasing beta-oxidation in a plant”, in line 1, and “wherein the level of oil or the level of at least one constituent of said oil is increased”, in line 20, is indefinite. It is not clear what or if there is a connection between the two parts of the claim.

In Claim 5, “an acyl-CoA thioesterase nucleotide sequence or fragment thereof” is indefinite. It is unclear whether the sequence or fragment thereof has an enzymatic activity.

In Claim 5, the claim does not recite a regeneration step and therefore, the plant of line 1 is the same said plant recited at the end of the claim. Further, the method claim is incomplete because it does not recite an expression step, and therefore there is no indication that expression of an acyl-CoA thioesterase nucleotide sequence is in any way related or even necessary to either decrease beta-oxidation or increase oil or an oil constituent in the plant.

In Claim 5, “at least one constituent of said oil” is indefinite. It is unclear what is comprised by constituent. The term “constituent” could refer to a non oil constituent or an oil constituent.

In Claims 5 and 21, “part” is indefinite. It is unclear what is comprised by “part”. The term is generic and could mean anything from lower part to upper part or sub-cellular part to extra-cellular part or leaf part or flower part.

In Claim 9, in line 2, after “expression”, insert --in--.

In Claim 12, line 2, delete “of”.

In Claims 12 and 24, “unusual” is indefinite. It is unclear what is unusual about a fatty acyl chain or a fatty acid or a triacylglycerol.

In Claims 21 and 30, line 20, “wherein the level of said acyl-CoA thioesterase is decreased or increased in said plant” is indefinite. It is unclear if the “said acyl-CoA thioesterase” recited at the end of the claim is the transgenic DNA recited at the beginning of the claim or not. For example, how could the level of “said acyl-CoA thioesterase” be decreased if the nucleotide sequence of 21(g) i.e. antisense is comprised in the construct?

In Claim 24, “capable of producing” is indefinite because it suggests that a plant may or may not produce.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Walbot V.; GenBank accession number AI600977 entered into the public database on April 13, 1999.

The claim is indefinite as discussed supra.

Walbot V. teaches an isolated EST from Zea Mays that has 99.0% sequence identity to SEQ ID NO: 1. The reference discloses all the limitations of the Claim 1.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Gordon-Kamm W. *et al.* The Plant Cell. July 1990, Vol. 2, pages 603-618; see figure 1 on page 604 in column 2.

Claims 1-3 are indefinite as discussed supra.

Gordon-Kamm teaches transformation of Maize with an expression vector comprising GUS, wherein expression is driven by the CAMV 35S promoter, and wherein the GUS gene comprises an adenine nucleotide that is complementary to any one of the thymine nucleotides of SEQ ID NO: 1.

Thus the reference teaches all the limitations of Claims 1-3.

Claims 5-14, 17, 21-22 and 24-30 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO: 1 and plants transformed with said polynucleotide.

All claims are rejected.

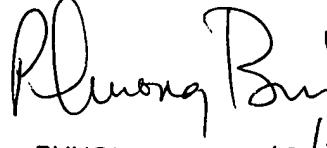
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

Russell Kallis Ph.D.
October 10, 2003


PHUONG T. BUI 10/20/03
PRIMARY EXAMINER